

SPL Pharma Subteam -- Drug Listing/ Establishment Registration Meeting Minutes – Nov 11, 2009

Topics of discussion:

1. Delisting: Trying to determine a solution that meets both FDA and Pharma needs
 - a. Situation: Product not marketed and no SPL exists. Currently the process necessitates that SPL be created with full COL – that will not be used subsequently. This is a huge amount of work for pharma – with no longer term use for the SPL. A most time/labor effective solution is desired.
 - b. Related issue adding complexity: Current data is not correct on NDC web site, which makes it more difficult to delist.
 - c. Once you delist them, the products are not removed from the NDC web site.
2. Export only – sub team will be forming a group to work through process issues: Michael will be setting up a meeting, but he hasn't been able to set up a convenient time.
3. Johnson and Johnson has multiple NDC codes for the same product-as a result of an acquisition. After an acquisition, the company changed its name and its NDC codes for the product. Both the old and new labels are posted on Daily Med. The company is currently working with FDA as to how to best manage this situation without having to maintain the old label until expiry of the last lot. This could potentially be a problem to many other pharma situations.
4. Problems getting an SPL off of Daily Med?
 - a. Ruth requested that Daily Med to remove an SPL – subsequent to them entering a market end date in the SPL. Daily Med forwarded the request back to FDA to manage.
 - b. Nobody has experience with a file being removed from Daily Med. Terry hypothesizes that this functionality has not been tested, and it may not be working. Thus Lonnie may have to remove these manually.
5. Has anyone had any problems with importation because of an SPL problem?
 - a. No pharma responded that have had problems with importing recently.
 - b. Marcia said that this is a problem with OTC products – in particular with monograph products. Monograph listings are not posted on Daily Med, and there is no posting for import staff to document that drug listing has been completed. Products are being held up at the border because there is no paper documentation. Lonnie has been helping to resolve these situations -- by investigating this situation and confirming to the import staff that the drug listing is in order.
6. Q&A Guidance document:
 - a. In the last SPL leadership meeting, Lonnie suggested that we review the following Q&A's, in particular, because there have been changes to these processes that are included in the Q&A document:
 - i. #3 Providing a link to the drug listing posting instead of having to include SPL in their submission to the review division.
 - ii. #9 Dates that Agency started accepting SPL R4.

- iii. #10 Should the applicant wait until availability of Reference Labeled Drug.
 - iv. #23 Including PPIs and MedGuides
 - v. #28 Will FDA make changes to R4 SPL before posting to the web?
 - vi. #31 How will SPL be transmitted to the web after Jun 1, 2009?
 - b. Who will be preparing responses to this draft guidance? The SPL Leadership team was going to talk about preparing a response. OTC team will also be discussing this.
 - c. Send any comments/questions/clarifications about the draft Q&A back to Michael. He will compile a list of topics to discuss.
7. New Business Operation Terms:
- a. Outsourcing human drug compounding: We are unclear as to what this refers to.
 - b. Jean will include a request in her letter to Leyla for clear definitions of the operations.
 - c. We are anxiously awaiting definitions for these terms.

Attending:

Michael Fahmy, Pat Cowall, Terry Brunone, Jean Kirkeleit-Davis, Marcia Howard, Ruth Kirkner, Gary Saner, Elisa Scordato Mandra, Dragan Obradovich, Paula Finn, Noah Willitsford, Stephan Strychar, Jackie Nelson, Beth Macioci, Gayle Lempka